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EXAMINER

CROW, ROBERT THOMAS

ART UNIT	PAPER NUMBER
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1634

NOTIFICATION DATE	DELIVERY MODE
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ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/526,402	Applicant(s) KIM ET AL.	
	Examiner Robert T. Crow	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 3,4 and 9-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2, 5-8, and 26-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

FINAL ACTION

Status of the Claims

1. This action is in response to papers filed 21 February 2008 in which claims 1, 5, 7, and 9 were amended, no claims were canceled, and new claims 26-29 were added. All of the amendments have been thoroughly reviewed and entered.

The objections to the claims in the previous Office Action are withdrawn in view of the amendments.

The previous rejections under 35 U.S.C. 112, second paragraph, are withdrawn in view of the amendments.

The previous rejections under 35 U.S.C. 102(b) and 35 U.S.C. 103(a) not reiterated below are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed and are addressed following the rejections necessitated by the amendments.

Claims 1-2, 5-8, and 26-29 are under prosecution.

Election/Restrictions

2. This application contains method claims 3-4 and 9-24, which are drawn to an invention nonelected with traverse in the reply filed on 20 June 2007. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Objections

3. Claim 2 is objected to because of the following informalities: claim 2 contains the recitation "which is used as protein chips, DNA chip, new drug screening chips, environmental assay chips, toxicity assay chips, or food bacteria assay chips" at the end of the claim. The claim is drawn to the singular biochip of claim 1, and therefore should only refer to a singular recitation of a chip with a proper article for each recitation of each different chip. Appropriate correction is required.

4. The following are new rejections necessitated by the amendments.

Claim Rejections - 35 USC § 112, First Paragraph

5. Claims 1-2 and 26-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. **This is a new matter rejection.** The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1, upon which claims 2 and 26-29 are drawn, is amended to recite "a free orientation without being immobilized" at the end of claim 1. Applicant cites page 5, lines 710 of the specification for support of the amendment. However, the citation merely recites the biomaterial "has a free orientation without a covalent bond." The broadly claimed "free orientation without being immobilized" encompasses other means for encapsulating a molecule in a gel that do not require a covalent bond; e.g., biotin/streptavidin interactions, or ionic/electrostatic interactions. A review of the specification yields no further recitation of a means to achieve a "free orientation." Thus, the broadly claimed "free orientation without being immobilized" encompasses embodiments other than "a free orientation without a covalent bond," and therefore constitutes new matter.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-2, 5-6, 8, and 26-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Kim et al (Biotechnology and Bioengineering, vol. 73, pages 331-337 (5 June 2001)).

Regarding claim 1, Kim et al teach a biochip. In a single exemplary embodiment, Kim et al teach Figure 1, which shows a biochip comprising a chip substrate in the form of a polyvinyl acetate coated glass slide having gel spots in the form of sol-gel microstructures in strips (i.e., spots) thereon. The sol-gel spots are immobilized on the slide because the spots are retained by the polyvinyl acetate (i.e., PVAc) coating (page 336, column 1, last full paragraph). The gel spots have pores therein in the form of microchannels (page 332, column 1, first full paragraph), and active proteins, which are biomaterials, are contained within the sol-gel spots (Figure 1). The biomaterials have a free orientation without being immobilized because they are entrapped within the pores (i.e., microchannel network; page 332, column 1, first full paragraph and page 333, column 1).

Regarding claim 2, Kim et al teach the biochip of claim 1. The courts have held that “while features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function.” *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997). In addition, “[A]pparatus claims cover what a device *is*, not what a device *does*.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (emphasis in original). Therefore, the various uses recited in claim 2 (e.g., use as a protein chip) fail to define additional structural elements to the device of independent claim 1. Because Kim et al teach the structural elements of claim 1, claim 2 is also anticipated by Kim et al. See MPEP § 2114.

Regarding claim 5, Kim et al teach a chip substrate in the form of a glass slide coated with a coating solution consisting of polyvinyl acetate (i.e., PVAc, Figure 1) having a molecular weight of 130,000 (page 332, “Materials” section) dissolved in methylene chloride (page 33, column 1).

Regarding claim 6, the substrate of claim 5 is discussed above. The courts have stated:

“[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). See MPEP§ 2113.

While Kim et al do not specifically teach spin coating, these limitations are part of the process of making the chip substrate rather than structural limitations of the chip substrate. Because Kim et al teach the structural elements of independent claim 5, claim 6 is also anticipated by Kim et al.

Regarding claim 8, Kim et al teach the chip substrate of claim 5, wherein the substrate has a slide shape; namely, the substrate is a slide (Figure 1).

Regarding claims 26-27, Kim et al teach the biochip of claim 1, wherein the biomaterials are IgG (page 333, column 1), which are antigens to anti-human polyvalent IgG (i.e., claim 27) and are proteins (i.e., claim 28).

It is noted that the broadly claimed “antigens or antibodies for infections disease diagnosis” of claim 27 does not necessarily require the antigens to be “for infections disease diagnosis” due to the placement of the word “or” in the recitation.

8. Claims 1-2 and 26-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Anderson et al (U.S. Patent Application Publication No. US 2002/0015952 A1, published 7 February 2002).

Regarding claim 1, Anderson et al teach a biochip. In a single exemplary embodiment, Anderson et al teach a biochip comprising a chip substrate in the form of sectioned bundles of tubes (paragraph 0063) bonded in a flat parallel array (Figure 1 and paragraph 0068). Each tube (i.e., tubule) contains a different entrapped biological agent of interest (i.e., biomaterial; paragraph 0012) which is entrapped within porous gel beads (paragraph 0058). Because the biomaterial is entrapped within porous gel beads, the biomaterials have a free orientation without being immobilized. The bundled sectioned tubes of the

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chip form spots (paragraph 0191). In addition, a review of the specification yields no limiting definition of a “spot” as being derived from the deposition of a gel on a substrate. Thus, the claim has been given the broadest reasonable interpretation consistent with the teachings of the specification regarding a “spot” (*In re Hyatt*, 211 F.3d1367, 1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000) (see MPEP 2111 [R-1])).

Regarding claim 2, Anderson et al teach the biochip of claim 1. As noted above, apparatus claims cover what a device *is*, not what a device *does*.” Therefore, the various uses recited in claim 2 (e.g., use as a protein chip) fail to define additional structural elements to the device of independent claim 1. Because Anderson et al teach the structural elements of claim 1, claim 2 is also anticipated by Anderson et al.

Regarding claim 26, Anderson et al teach the biochip of claim 1, wherein the biomaterials (i.e., molecules of interest) are DNA (i.e., nucleic acids) or proteins (paragraph 0052 and 0112).

Regarding claim 27, Anderson et al teach the biochip of claim 26, wherein the proteins are antigens for infections disease diagnosis (paragraph 0063).

It is also noted that claim 27 not further limiting in the embodiment wherein claim 26 is drawn to DNA as a biomaterial. Thus, in the embodiment of claim 26 wherein the biomaterials are DNA, Anderson et al anticipate both claim 26 and the non-limiting embodiment of claim 27 described above.

9. Claims 1-2 and 26-27 are rejected under 35 U.S.C. 102(a) as being anticipated by Dordick et al (PCT International Application Publication No. WO 03/038131 A1, published 8 May 2003).

Regarding claim 1, Dordick et al teach a biochip. In a single exemplary embodiment, Dordick teach a plurality of independent micromatrices fixed (i.e., mounted and immobilized on) a solid support, which is a chip substrate (page 5). The micromatrices are permeable and encapsulate an enzyme (page 4), which is a biomaterial. Because the enzymes are encapsulated withing the micromatrices, the enzymes (i.e., biomaterials) have a free orientation without being immobilized.

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Regarding claim 2, Dordick et al teach the biochip of claim 1. As noted above, apparatus claims cover what a device *is*, not what a device *does*." Therefore, the various uses recited in claim 2 (e.g., use as a protein chip) fail to define additional structural elements to the device of independent claim 1. Because Dordick et al teach the structural elements of claim 1, claim 2 is also anticipated by Dordick et al.

Regarding claim 26, Dordick et al teach the biochip of claim 1, wherein the biomaterials (i.e., test compositions) are DNA or proteins (pages 7-8).

Regarding claim 27, Dordick et al teach the biochip of claim 26, wherein the proteins are antibodies indicative of a cancerous state (pages 7-8).

It is also noted that claim 27 not further limiting in the embodiment wherein claim 26 is drawn to DNA as a biomaterial. Thus, in the embodiment of claim 26 wherein the biomaterials are DNA, Dordick et al anticipate both claim 26 and the non-limiting embodiment of claim 27 described above.

10. Claims 1-2 and 26-27 are rejected under 35 U.S.C. 102(e) as being anticipated by Dordick et al (U.S. Patent Application Publication No. US 2003/0162284 A1, filed 1 November 2002).

Regarding claim 1, Dordick et al teach a biochip. In a single exemplary embodiment, Dordick teach a plurality of independent micromatrices fixed (i.e., mounted and immobilized on) a solid support, which is a chip substrate (paragraph 0020). The micromatrices are permeable and encapsulate an enzyme (paragraph 0016), which is a biomaterial. Because the enzymes are encapsulated within the micromatrices, the enzymes (i.e., biomaterials) have a free orientation without being immobilized.

Regarding claim 2, Dordick et al teach the biochip of claim 1. As noted above, apparatus claims cover what a device *is*, not what a device *does*." Therefore, the various uses recited in claim 2 (e.g., use as a protein chip) fail to define additional structural elements to the device of independent claim 1. Because Dordick et al teach the structural elements of claim 1, claim 2 is also anticipated by Dordick et al.

Regarding claim 26, Dordick et al teach the biochip of claim 1, wherein the biomaterials (i.e., test compositions) are DNA or proteins (paragraphs 0028-0029).

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Regarding claim 27, Dordick et al teach the biochip of claim 26, wherein the proteins are antibodies (i.e., paragraph 0029) indicative of a cancerous state (paragraph 0028).

It is also noted that claim 27 not further limiting in the embodiment wherein claim 26 is drawn to DNA as a biomaterial. Thus, in the embodiment of claim 26 wherein the biomaterials are DNA, Dordick et al anticipate both claim 26 and the non-limiting embodiment of claim 27 described above.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 1, 5, 7, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al (Biotechnology and Bioengineering, vol. 73, pages 331-337 (5 June 2001)) in view of Simon et al (U.S. Patent No. 5,569,607, issued 29 October 1996).

It is noted that this rejection applies to claims 1 and 5 to the extent that it they drawn to the embodiments of dependent claims 28 and 7, respectively.

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Regarding claim 7, Kim et al teach the chip substrate of claim 5 in the form of a glass slide coated with a coating solution consisting of polyvinyl acetate (i.e., PVAc, Figure 1) having a molecular weight of 130,000 (page 332, "Materials" section) dissolved in methylene chloride (page 33, column 1).

Kim et al do not teach the substrate is a polycarbonate substrate.

However, Simon et al teach a slide substrate made of polycarbonate, which has the added advantage of being made by plastic injection molding, thereby producing a precision slide by simple manufacturing techniques (column 1, line 59-column 2, line 10). Thus, Simon et al teach the known technique of using a polycarbonate substrate.

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the chip substrate as taught by Kim et al by using the polycarbonate substrate of Simon et al as the chip substrate to arrive at the instantly claimed invention with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in a chip substrate having the added advantage of having a precision slide made by simple manufacturing techniques as explicitly taught by Simon et al (column 1, line 59-column 2, line 10). In addition, it would have been obvious to the ordinary artisan that the known technique of using the polycarbonate substrate of Simon et al could have been used as the chip substrate of Kim et al of with predictable results because the polycarbonate substrate of Simon et al predictably results in a substrate useful for evaluation of specimen liquids.

Regarding claim 28, Kim et al teach the biochip of claim 1. In a single exemplary embodiment, Kim et al teach Figure 1, which shows a biochip comprising a chip substrate in the form of a polyvinyl acetate coated glass slide having gel spots in the form of sol-gel microstructures in strips (i.e., spots) thereon. The sol-gel spots are immobilized on the slide because the spots are retained by the polyvinyl acetate (i.e., PVAc) coating (page 336, column 1, last full paragraph). The gel spots have pores therein in the form of microchannels (page 332, column 1, first full paragraph), and active proteins, which are biomaterials, are contained within the sol-gel spots (Figure 1). The biomaterials have a free orientation

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without being immobilized because they are entrapped within the pores (i.e., microchannel network; page 332, column 1, first full paragraph and page 333, column 1).

Kim et al do not teach the substrate is a polycarbonate substrate.

However, Simon et al teach a slide substrate made of polycarbonate, which has the added advantage of being made by plastic injection molding, thereby producing a precision slide by simple manufacturing techniques (column 1, line 59-column 2, line 10). Thus, Simon et al teach the known technique of using a polycarbonate substrate.

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the biochip as taught by Kim et al by using the polycarbonate substrate of Simon et al as the chip substrate to arrive at the instantly claimed invention with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in a biochip having the added advantage of having a precision slide made by simple manufacturing techniques as explicitly taught by Simon et al (column 1, line 59-column 2, line 10). In addition, it would have been obvious to the ordinary artisan that the known technique of using the polycarbonate substrate of Simon et al could have been used as the chip substrate of Kim et al of with predictable results because the polycarbonate substrate of Simon et al predictably results in a substrate useful for evaluation of specimen liquids.

14. Claims 1, 26-27, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al (Biotechnology and Bioengineering, vol. 73, pages 331-337 (5 June 2001)) in view of Croxson (U.S. Patent No. 5,108,891, issued 28 April 1992).

It is noted that this rejection applies to claims 1 and 26 to the extent that it they drawn to the embodiments of dependent claims 29 and 27, respectively.

It is also noted that while claim 27 has been broadly rejected under 35 U.S.C. 102(b) as described above in Section 7, the claim is also obvious using the alternative interpretation outlined below.

Regarding claims 27 and 29, Kim et al teach the biochip of claim 1. In a single exemplary embodiment, Kim et al teach Figure 1, which shows a biochip comprising a chip substrate in the form of a polyvinyl acetate coated glass slide having gel spots in the form of sol-gel microstructures in strips (i.e., spots) thereon. The sol-gel spots are immobilized on the slide because the spots are retained by the polyvinyl acetate (i.e., PVAc) coating (page 336, column 1, last full paragraph). The gel spots have pores therein in the form of microchannels (page 332, column 1, first full paragraph), and active proteins, which are biomaterials, are contained within the sol-gel spots (Figure 1). The biomaterials have a free orientation without being immobilized because they are entrapped within the pores (i.e., microchannel network; page 332, column 1, first full paragraph and page 333, column 1).

Kim et al teach also the biochip of claim 26, wherein the biomaterials are proteins; namely, IgG (page 333, column 1), which is a protein.

Kim et al do not specifically teach the protein is HIV p24 (i.e., claims 27 and 29).

However, Croxson teaches the binding of molecules to protein HIV p24 (Abstract), wherein HIV p24 has the added advantage of being an indicator of the progression of HIV to AIDS (column 1, lines 40-67). Thus, Croxson teaches the known technique of binding molecules to HIV p24.

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the biochip as taught by Kim et al by using the HIV p24 protein of Croxson as the biomaterial on the biochip of Kim et al to arrive at the instantly claimed invention with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in a biochip having the added advantage of allowing the assays performed with the biochip to indicate the progression of HIV to AIDS as explicitly taught by Croxson (column 1, lines 40-67). In addition, it would have been obvious to the ordinary artisan that the known technique of using the HIV p24 of Croxson could have been used as the biomaterial in the biochip of Kim et al with predictable results because the HIV p24 of Croxson predictably results in a substrate useful for evaluation of the HIV progression in a patient.

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15. Claims 5-6 and 8 are rejected under 35 U.S.C. 103(a) as being obvious over Anderson et al (U.S. Patent Application Publication No. US 2002/0015952 A1, published 7 February 2002) in view of Kim et al (Biotechnology and Bioengineering, vol. 73, pages 331-337 (5 June 2001)).

Regarding claim 5, Anderson et al teach a chip substrate. In a single exemplary embodiment, Anderson et al teach a chip substrate in the form of sectioned bundles of tubes (paragraph 0063) bonded in a flat parallel array (Figure 1 and paragraph 0068) and mounted on a slide (paragraph 0030). Each tube (i.e., tubule) contains a different entrapped biological agent of interest (i.e., biomaterial; paragraph 0012) which is entrapped within porous gel beads (paragraph 0058). Because the biomaterial is entrapped within porous gel beads, the biomaterials have a free orientation without being immobilized. The bundled sectioned tubes of the chip form spots (paragraph 0191).

While Anderson et al also teach the slides are coated (paragraph 0134), Anderson et al do not specifically teach coating with polyvinyl acetate.

However, Kim et al teach a chip substrate in the form of a slide coated with a coating solution consisting of polyvinyl acetate (i.e., PVAc, Figure 1) having a molecular weight of 130,000 (page 332, "Materials" section) dissolved in methylene chloride (page 33, column 1), which a the added advantage of improving adhesion of gels to the slide (page 336, column 1). Thus, Kim et al teach the known technique of coating a slide with polyvinyl acetate.

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the coated chip substrate as taught by Anderson et al by coating the chip substrate with the polyvinyl acetate as taught by Kim et al to arrive at the instantly claimed invention with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in a chip substrate having the added advantage of improved adhesion of gels to the slide as explicitly taught by Kim et al (page 336, column 1). In addition, it would have been obvious to the ordinary artisan that the known technique of polyvinyl acetate coating as taught by Kim et al could have been used as the coating in the

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chip substrate of Anderson et al of with predictable results because the polyvinyl acetate coating as taught by Kim et al predictably results in a substrate with improved adhesion of the gels.

Regarding claim 6, the substrate of claim 5 is discussed above. The courts have stated:

“[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). See MPEP§ 2113.

Thus, while neither Anderson et al nor Kim et al specifically teach spin coating, these limitations are part of the process of making the chip substrate rather than structural limitations of the chip substrate. Because Anderson et al in view of Kim et al teach the structural elements of independent claim 5, claim 6 is obvious over Anderson et al in view of Kim et al.

Regarding claim 8, the substrate of claim 5 is discussed above. Anderson et al teach the substrate has a slide shape; namely, the substrate to which the tubes are mounted is a slide (paragraph 0030).

16. Claim 7 is rejected under 35 U.S.C. 103(a) as being obvious over Anderson et al (U.S. Patent Application Publication No. US 2002/0015952 A1, published 7 February 2002) in view of Kim et al (Biotechnology and Bioengineering, vol. 73, pages 331-337 (5 June 2001)) as applied to claim 5 above, and further in view of Simon et al (U.S. Patent No. 5,569,607, issued 29 October 1996).

Regarding claim 7, the chip substrate of claim 5 is discussed above in Section 15.

Neither Anderson et al nor Kim et al teach the substrate is a polycarbonate substrate.

However, Simon et al teach a slide substrate made of polycarbonate, which has the added advantage of being made by plastic injection molding, thereby producing a precision slide by simple manufacturing techniques (column 1, line 59-column 2, line 10). Thus, Simon et al teach the known technique of using a polycarbonate substrate.

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the chip substrate as taught by Anderson et al in view of Kim et al by using the polycarbonate substrate of Simon et al as the chip substrate to arrive at the instantly claimed invention with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in a chip substrate having the added advantage of having a precision slide made by simple manufacturing techniques as explicitly taught by Simon et al (column 1, line 59-column 2, line 10). In addition, it would have been obvious to the ordinary artisan that the known technique of using the polycarbonate substrate of Simon et al could have been used as the chip substrate of Anderson et al in view of Kim et al of with predictable results because the polycarbonate substrate of Simon et al predictably results in a substrate useful for evaluation of specimen liquids.

17. Claims 1, 26-27, and 29 are rejected under 35 U.S.C. 103(a) as being obvious over Anderson et al (U.S. Patent Application Publication No. US 2002/0015952 A1, published 7 February 2002) in view of Croxson (U.S. Patent No. 5,108,891, issued 28 April 1992).

It is noted that this rejection applies to claims 1 and 26 to the extent that it they drawn to the embodiments of dependent claims 29 and 27, respectively.

It is also noted that while claim 27 has been broadly rejected under 35 U.S.C. 102(b) as described above in Section 8, the claim is also obvious using the alternative interpretation outlined below.

Regarding claims 27 and 29, Anderson et al teach the biochip of claim 1. In a single exemplary embodiment, Anderson et al teach a biochip comprising a chip substrate in the form of sectioned bundles of tubes (paragraph 0063) bonded in a flat parallel array (Figure 1 and paragraph 0068). Each tube (i.e., tubule) contains a different entrapped biological agent of interest (i.e., biomaterial; paragraph 0012) which is entrapped within porous gel beads (paragraph 0058). Because the biomaterial is entrapped within porous gel beads, the biomaterials have a free orientation without being immobilized. The

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bundled sectioned tubes of the chip form spots (paragraph 0191). In addition, a review of the specification yields no limiting definition of a "spot" as being derived from the deposition of a gel on a substrate.

Thus, the claim has been given the broadest reasonable interpretation consistent with the teachings of the specification regarding a "spot."

Anderson et al also teach the biochip of claim 26, wherein the biomaterials (i.e., molecules of interest) are proteins (paragraph 0052 and 0112).

Anderson et al do not specifically teach the protein is HIV p24 (i.e., claims 27 and 29).

However, Croxson teaches the binding of molecules to protein HIV p24 (Abstract), wherein HIV p24 has the added advantage of being an indicator of the progression of HIV to AIDS (column 1, lines 40-67). Thus, Croxson teaches the known technique of binding molecules to HIV p24.

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the biochip as taught by Anderson et al by using the HIV p24 protein of Croxson as the biomaterial on the biochip of Kim et al to arrive at the instantly claimed invention with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in a biochip having the added advantage of allowing the assays performed with the biochip to indicate the progression of HIV to AIDS as explicitly taught by Croxson (column 1, lines 40-67). In addition, it would have been obvious to the ordinary artisan that the known technique of using the HIV p24 of Croxson could have been used as the biomaterial in the biochip of Anderson et al of with predictable results because the HIV p24 of Croxson predictably results in a substrate useful for evaluation of the HIV progression in a patient.

18. Claims 1 and 28 are rejected under 35 U.S.C. 103(a) as being obvious over Anderson et al (U.S. Patent Application Publication No. US 2002/0015952 A1, published 7 February 2002) in view of Simon et al (U.S. Patent No. 5,569,607, issued 29 October 1996).

It is noted that this rejection applies to claim 1 to the extent that it is drawn to the embodiment of dependent claim 28.

Regarding claim 28, Anderson et al teach the biochip of claim 1. In a single exemplary embodiment, Anderson et al teach a biochip comprising a chip substrate in the form of sectioned bundles of tubes (paragraph 0063) bonded in a flat parallel array (Figure 1 and paragraph 0068). Each tube (i.e., tubule) contains a different entrapped biological agent of interest (i.e., biomaterial; paragraph 0012) which is entrapped within porous gel beads (paragraph 0058). Because the biomaterial is entrapped within porous gel beads, the biomaterials have a free orientation without being immobilized. The bundled sectioned tubes of the chip form spots (paragraph 0191). In addition, a review of the specification yields no limiting definition of a "spot" as being derived from the deposition of a gel on a substrate. Thus, the claim has been given the broadest reasonable interpretation consistent with the teachings of the specification regarding a "spot."

Anderson et al do not teach the substrate is a polycarbonate substrate.

However, Simon et al teach a slide substrate made of polycarbonate, which has the added advantage of being made by plastic injection molding, thereby producing a precision slide by simple manufacturing techniques (column 1, line 59-column 2, line 10). Thus, Simon et al teach the known technique of using a polycarbonate substrate.

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the biochip as taught by Anderson et al by using the polycarbonate substrate of Simon et al as the chip substrate to arrive at the instantly claimed invention with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in a biochip having the added advantage of having a precision slide made by simple manufacturing techniques as explicitly taught by Simon et al (column 1, line 59-column 2, line 10). In addition, it would have been obvious to the ordinary artisan that the known technique of using the polycarbonate substrate of Simon et al could have been used as the chip

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substrate of Anderson et al of with predictable results because the polycarbonate substrate of Simon et al predictably results in a substrate useful for evaluation of specimen liquids.

Response to Arguments

19. Applicant's arguments with respect to the previous rejections of the claims have been considered but are moot in view of the new ground(s) of rejection necessitated by the amendments.

It is noted, however, that on page 10 of the Remarks filed 21 February 2008, Applicant cited an excerpt from Wikipedia regarding cyclic olefin polymers. Applicant did not cite this document on an Information Disclosure Statement; therefore, the examiner has listed it on the "Notice or References Cited" included with this Office Action.

Conclusion

20. No claim is allowed.

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

22. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert T. Crow whose telephone number is (571)272-1113. The examiner can normally be reached on Monday through Friday from 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert T. Crow/
Examiner, Art Unit 1634

Robert T. Crow
Examiner
Art Unit 1634

/Diana B. Johannsen/
Primary Examiner, Art Unit 1634